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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,636	02/02/1999	ELLEN M. HEATH	41140-0003	8977

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HELLER EHRMAN LLP
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/241,636

Applicant(s)

HEATH ET AL.

Examiner

Jeanine A. Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: NONE.
Claim(s) objected to: NONE.
Claim(s) rejected: 63-109.
Claim(s) withdrawn from consideration: NONE.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____


Jeanine A. Goldberg
Examiner
Art Unit: 1634

Continuation of 11. does NOT place the application in condition for allowance because: A) It is noted that the IDS filed July 6, 2007 has not been considered. As provided in 1.97, An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section, provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:

- (1) The statement specified in paragraph (e) of this section; AND
- (2) The fee set forth in § 1.17(p).

Here, the IDS does not contain the required statement.

B) With respect to the 103 rejection over Harvey in view of Rudi, the response asserts that Harvey teaches "a chaotropic salt should inactivate any nucleic acid amplification inhibitors present in the biological sample." This argument has been reviewed but is not persuasive. Harvey teaches "Preferably, a chaotropic salt should inactivate any nucleic acid amplification inhibitors present in the biological source, by precipitation, by inducing the inhibitor to irreversibly bind to the matrix, or by causing substantially irreversible denaturation of the inhibitor. Suitable chaotropic salts include guanidinium salts such as guanidine isothiocyanate, guanidine thiocyanate, guanidine hydrochloride, sodium iodide, sodium perchlorate, potassium iodide, sodium (iso)thiocyanate, urea, or combinations thereof. The salts can be impregnated about the absorbent material by contacting the absorbent material with a solution containing the chaotropic salt. Such solutions can contain from about 0.1M to 6.0M salt concentrations, preferably 0.5M to 2.0M. The absorbent material is then dried."

The MPEP provides in 2123 that the reference may be used for all that it teaches. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Here, Harvey teaches "preferably" that the chaotropic salt should inactivate any inhibitors. However, Harvey further continues to provide particular ranges including 0.1M to 6.0M and 0.5M-2.0M concentrations. As evidenced by Ahmed, these concentrations do not denature the RNA digesting function of the RNAses.

The response further asserts that Rudi does not teach a method for binding cells to a solid support treated with a lysing reagent and a RNA digesting enzyme because Rudi teaches binding of intact cells to the solid support. This argument has been reviewed, but is not persuasive. The teachings of Rudy have been used to illustrate that RNAses may be used to remove RNA from a sample.

C) The response traverses the rejection over Boom in view of Shieh and Rudi. It is noted that these arguments are first presented in the after final rejection. The previous response failed to provide any substantive arguments in response to this rejection. An affidavit or other evidence filed after a final rejection, but before or on the same date of filing an appeal, may be entered upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented in compliance with 37 CFR 1.116(e). The prosecution of an application before the examiner should ordinarily be concluded with the final action.

Boom teaches using a chaotropic substance which is capable of altering structure, however Boom does not require that the chaotropic substance alters the structure. It is well known in the art, as suggested by the response and Ahmed that different concentrations of chotropic agents are capable of altering structure. Moreover Boom specifically teaches using GuSCN, for example.

The response asserts that Boom teaches that buffers for elution, if desired, may contain RNAsin. As noted above, a reference may be used for all that it teaches. Boom clearly contemplates and teaches using both buffers with and without RNAsin. Thus, unlike the response suggests Boom does not teaches the undesirability of RNase blanketly, but rather contemplates buffers with and without the RNase inhibitor.

Shieh teaches coating a solid support with a lysing reagent. Shieh teaches the desirability of preparing a device comprising a lysis reagent.

Given the broad teachings of Boom, Shieh and Rudi, the combination of references teaches the claimed invention.

D) With respect to Deggerdal in view of Shieh and Rudi, the prior art teaches the claimed method.

Shieh teaches coating a solid support with a lysing reagent. Shieh teaches the desirability of preparing a device comprising a lysis reagent.

The response further asserts that Rudi does not teach a method for binding cells to a solid support treated with a lysing reagent and a RNA digesting enzyme because Rudi teaches binding of intact cells to the solid support. This argument has been reviewed, but is not persuasive. The teachings of Rudy have been used to illustrate that RNAses may be used to remove RNA from a sample.

The response asserts that Deggerdal does not teaches a solid support treated with a lysing reagent and a RNA digesting enzyme. As noted above, Shieh teaches coating a solid support with a lysing reagent.

Since Deggerdal teaches a method for lysing and analyzing DNA using a solid support, Shieh teaches coating a solid support with a lysing reagent and Rudi teaches adding an RNase to remove RNA from the sample, the combination of prior art teaches all of the limitations of the instant claims and renders obvious the claimed invention.

E) The response identifies a typographical error in the rejection over Boom, Shieh, Rudi and Deggerdal. It appears as though claims 95 and 97 are the two claims to be rejected.

F) The response argues that all of the additional rejections are on dependent claims and presents no additional arguments. Thus, for the reasons of record and presented above, these rejections are maintained.

A handwritten signature in black ink, appearing to read "J. Goldberg". The signature is written in a cursive, flowing style with a large initial "J" and a long, sweeping underline.